

PATENT

Attorney Docket No. HOGAN-04448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kirk Hogan
Serial No.: 09/613,887
Filed: July 11, 2000
Entitled: Methods and Compositions for Perioperative Genomic Profiling

Group No.: 1655
Examiner: J.E. Goldberg

**SECOND DECLARATION OF KIRK HOGAN, M.D.
UNDER 37 C.F.R. §1.132**

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: July 8, 2002By: Susan M. McClintock

Susan M. McClintock

Madam:

1. I, Kirk Hogan, am the inventor of the subject matter embodied in the above-identified patent application.
2. I am not aware of any case where physicians have carried out genomic profiling in the perioperative period using a heterogeneous assay (other than my own work).
3. Even to this day, to my knowledge, the ordinary artisan does not clearly recognize the benefit of testing an individual for genetic markers prior to surgery in order to generate a perioperative genomic profile.
4. This is evidenced, for example, in the 2002 manuscript "Practice Advisory for Preanesthesia Evaluation: A Report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation."

5. To prepare the Practice Advisory the 12 member Task Force used a six step process. First, they reached consensus on the criteria for evidence of effectiveness of preanesthesia evaluation. Second, original published research studies relevant to these issues were reviewed. Third, consultants who had expertise or interest in preanesthesia evaluation, and who had practiced or worked in various settings (e.g., academic and private practice) were asked to (1) participate in opinion surveys on the effectiveness of various preanesthesia evaluation strategies, and (2) review and comment on the draft reports of the Task Force. Fourth, opinions about various elements of this Practice Advisory were solicited from a random sample of active members of ASA. Fifth, the Task Force held several open forums at major national anesthesia meetings to solicit input on key concepts of this Advisory. Sixth, all available information was used to build a consensus within the Task Force on the Advisory.

6. The Task Force concludes "*Routine preoperative tests (i.e., tests intended to discover a disease or disorder in an asymptomatic patient) do not make an important contribution to the process of perioperative assessment and management of the patient by the anesthesiologist.*" (emphasis in original)

7. The Task Force Practice Advisory for Preanesthesia Evaluation does not teach that perioperative genetic testing should be carried out.

8. The Task Force Practice Advisory for Preanesthesia Evaluation does not provide guidelines for selecting markers useful for perioperative genetic testing.

9. The Task Force Practice Advisory for Preanesthesia Evaluation does not advocate, consider or even mention genetic testing, use of genetic markers, or generation of genomic profiles in the perioperative interval.

10. The Task Force Practice Advisory for Preanesthesia Evaluation demonstrates that both experts and artisans of ordinary skill in the art do not believe, or clearly recognize, that perioperative genetic testing should be carried out.

11. The ordinary artisan did not clearly recognize the benefit of testing an individual prior to surgery and subjection to anesthesia for known genetic markers associated with conditions triggered by anesthesia or surgery at the time the invention was made.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be

true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated:

7/8/02

Signed:

KH

Kirk Hogan

SPECIAL ARTICLE

Anesthesiology 2002; 96:485-96

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Practice Advisory for Preanesthesia Evaluation

A Report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care where scientific evidence is insufficient to develop an evidence-based model. Practice advisories provide a synthesis of opinion from experts, open forums, and other public sources. Practice advisories report the current state of scientific literature, but are not supported by literature to the same degree as standards or guidelines due to the lack of sufficient numbers of adequately controlled studies.

Advisories are not intended as guidelines, standards, or absolute requirements. The use of practice advisories cannot guarantee any specific outcome. They may be adopted, modified, or rejected according to clinical needs and constraints. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

Definition of Preanesthesia Evaluation

The literature does not provide a standard definition for preanesthesia evaluation. For this Practice Advisory, the preanesthesia evaluation is defined as the process of clinical assessment that precedes the delivery of anesthesia care for surgery and for nonsurgical procedures. The preanesthesia evaluation is the responsibility of the anesthesiologist.

Preanesthesia evaluation consists of the consideration of information from multiple sources that may include

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Developed by the Task Force on Preanesthesia Evaluation: L. Reuven Pasternak, M.D. (Chair), Baltimore, Maryland; James F. Arenas, M.D., Houston, Texas; Robert A. Caplan, M.D., Seattle, Washington; Richard T. Connis, Ph.D., Woodinville, Washington; Lee A. Fleisher, M.D., Baltimore, Maryland; Richard Flowerdew, M.B., Portland, Maine; Barbara S. Gold, M.D., Minneapolis, Minnesota; James F. Mayhew, M.D., League City, Texas; David G. Nickinovich, Ph.D., Bellevue, Washington; Linda Jo Rice, M.D., St. Petersburg, Florida; Michael F. Roizen, M.D., Chicago, Illinois; Rebecca S. Twersky, M.D., Brooklyn, New York

Submitted for publication November 5, 2001. Accepted for publication November 5, 2001. Support was provided by the American Society of Anesthesiologists, under the direction of James F. Arenas, M.D., Chair of the Committee on Practice Parameters. Approved by the House of Delegates, October 17, 2001.

The accompanying Web site enhancement is a bibliography.

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the patient's medical records, interview, physical examination, and findings from medical tests and evaluations. As part of the preanesthesia evaluation process, the anesthesiologist may choose to consult with other healthcare professionals to obtain information or services that are relevant to perioperative anesthetic care. Preoperative tests, as a component of the preanesthesia evaluation, may be indicated for various purposes, including but not limited to (1) discovery or identification of a disease or disorder that may affect perioperative anesthetic care, (2) verification or assessment of an already known disease, disorder, medical or alternative therapy that may affect perioperative anesthetic care, and (3) formulation of specific plans and alternatives for perioperative anesthetic care. For this Advisory, *perioperative* refers to the care surrounding operations and procedures.

The assessments made in the process of a preanesthesia evaluation may be used to educate the patient, organize resources for perioperative care, and formulate plans for intraoperative care, postoperative recovery, and perioperative pain management.

Purposes of the Advisory for Preanesthesia Evaluation

The purposes of this Advisory are to (1) assess the currently available evidence pertaining to the healthcare benefits of preanesthesia evaluation, (2) offer a reference framework for the conduct of preanesthesia evaluation by anesthesiologists, and (3) stimulate research strategies that can assess the healthcare benefits of a preanesthesia evaluation.

Focus

A preanesthesia evaluation is considered a basic element of anesthesia care. Therefore, the focus of this Advisory is the assessment of evidence pertaining to the content and timing of a preanesthesia evaluation. The interactions between the preanesthesia evaluation, preoperative testing, and perioperative care are beyond the scope and mandate of the Task Force. Informed consent, often undertaken at the same time as the preanesthesia evaluation, is also beyond the scope of this Advisory.

Application

This Advisory is intended for use by anesthesiologists and those who provide care under the direction of an anesthesiologist. The Advisory applies to patients of all ages who are scheduled to receive general anesthesia, regional anesthesia, moderate or deep sedation for elective surgical and nonsurgical procedures. The Advisory does not address the selection of anesthetic technique nor the preanesthesia evaluation of patients requiring urgent or emergency surgery or anesthetic management provided on an urgent basis in other locations (e.g., emergency rooms).

Criteria for Anesthesia Intervention, Testing, and Consultation

Any evaluations, tests, and consultations required for a patient are done with the reasonable expectation that such activities will result in benefits that exceed the potential adverse effects. Potential benefits may include a change in the content or timing of anesthetic management or perioperative resource utilization that may improve the safety and effectiveness of anesthetic processes involved with perioperative care. Potential adverse effects may include interventions that result in injury, discomfort, inconvenience, delays, or costs that are not commensurate with the anticipated benefits.

Task Force Members and Consultants

The American Society of Anesthesiologists (ASA) appointed a task force of 12 members to (1) review published evidence; (2) obtain expert and public consensus opinion; and (3) create a consensus-based assessment of currently available scientific literature and opinion. The ASA Task Force members consisted of anesthesiologists in both private and academic practices from various geographic areas of the United States, and methodologists from the ASA Committee on Practice Parameters.

The Task Force used a six-step process. First, they reached consensus on the criteria for evidence of effectiveness of preanesthesia evaluation. Second, original published research studies relevant to these issues were reviewed. Third, consultants who had expertise or interest in preanesthesia evaluation, and who practiced or worked in various settings (e.g., academic and private practice) were asked to (1) participate in opinion surveys on the effectiveness of various preanesthesia evaluation strategies, and (2) review and comment on draft reports of the Task Force. Fourth, opinions about various elements of this Practice Advisory were solicited from a random sample of active members of the ASA. Fifth, the Task Force held several open forums at major national anesthesia meetings to solicit input on the key concepts

of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

Availability and Strength of Evidence

Practice advisories are developed by a systematic, consensus-based process. In contrast to evidence-based guidelines, practice advisories lack the support of a sufficient number of adequately controlled scientific studies to permit aggregate analyses of data with rigorous statistical techniques such as meta-analysis. Nonetheless, literature-based evidence for practice advisories is available from limited controlled trials, case reports, descriptive studies, and by the assessment of the strengths and weaknesses of published studies. This literature often permits the identification of recurring patterns of clinical practice. Opinion surveys often reveal similar patterns. The advisory statements contained in a practice advisory represent a consensus-based distillation of the clearest patterns of agreement or disagreement.

Advisory Statements

Preanesthesia History and Physical Examination

Impact. A preanesthesia history and physical examination precedes the ordering, requiring, or performance of specific preanesthesia tests, and consists of (1) evaluation of pertinent medical records, (2) patient interview(s), and (3) physical examination. No controlled trials of the clinical impact of performing a preanesthesia medical records review or physical examination were found. Several studies reported specific perioperative outcomes (e.g., cardiac, respiratory, renal, hemorrhagic) occurring in patients with specific preexisting conditions (e.g., hypertension, previous myocardial infarction, smoking, pulmonary disease, and age).¹⁻⁶³ Such conditions often are noted in a patient's medical record. Additional studies were examined that reported preexisting conditions (e.g., airway abnormalities, cardiopulmonary disorders) detected during a preanesthesia examination or interview.^{6,28,44,47,49,59,64-91} Five of these studies resulted in changes in resource management.^{49,64,74,82,84} These studies were not controlled trials and were not considered sufficiently rigorous to provide unequivocal evidence of the value of performing a preanesthetic medical records review or physical examination.

Advisory

The Task Force believes that the assessment of anesthetic risks associated with the patient's medical condi-

Table 1. Timing of the Initial Assessment of Pertinent Medical Records—Survey Opinions

| Surgical Invasiveness | High | | Medium | | Low | |
|---------------------------------|-------------------------|--------------------------|-------------------------|--------------------------|-------------------------|--------------------------|
| | Consultants (N = 72) | ASA Members (N = 234) | Consultants (N = 72) | ASA Members (N = 231) | Consultants (N = 72) | ASA Members (N = 233) |
| Prior to the day of surgery | 89% | 75% | 58% | 33% | 17% | 11% |
| On or before the day of surgery | 11% | 24% | 39% | 61% | 69% | 59% |
| Only on the day of surgery | 0% | 1% | 3% | 6% | 14% | 30% |

ASA = American Society of Anesthesiologists.

tions, therapies, alternative treatments, surgical and other procedures, and of options for anesthetic techniques is an essential component of basic anesthetic practice. Benefits may include, but are not limited to, the safety of perioperative care, optimal resource utilization, improved outcomes, and patient satisfaction.

Timing. The activities encompassed by a preanesthesia history and physical examination occur over a variable period of time. The timing of an initial preanesthesia evaluation is guided by such factors as patient demographics, clinical conditions, type and invasiveness of procedure, and the nature of the healthcare system. Three options that practices utilize for the timing of an initial preanesthesia evaluation are (1) always prior to the day of surgery, (2) either on or before the day of surgery, and (3) only on the day of surgery.

Although no controlled trials addressing the timing of a preanesthesia evaluation were found, survey opinions from expert consultants and a random sample of ASA members were obtained to examine potential clinical influences (*i.e.*, patient severity of disease and surgical invasiveness) on timing decisions. Consultant and ASA membership opinions regarding the timing of an initial assessment of pertinent medical records for high, medium, and low levels of surgical invasiveness, independent of medical condition, are reported in table 1. The majority of consultants and ASA members agree that, for high surgical invasiveness, the initial assessment of pertinent

medical records should be done prior to the day of surgery by anesthesia staff. For medium surgical invasiveness, the majority of consultants indicate that the initial assessment of pertinent medical records should be done prior to the day of surgery by anesthesia staff, although the majority of ASA members indicate that the initial assessment may be done on or before the day of surgery. For low surgical invasiveness, the majority of consultants and ASA members agree that the initial assessment may be done on or before the day of surgery.

Consultant and ASA membership opinions regarding the timing of an initial preanesthesia interview and physical examination for high and low severities of disease are reported in table 2. The majority of consultants and ASA members agree that, for patients with high severity of disease, it is preferable that the interview and physical examination be done before the day of surgery by anesthesia staff. For low severity of disease and high surgical invasiveness, consultants and ASA members agree that it is preferable that the interview and physical examination be done prior to the day of surgery. For patients with low severity of disease and medium or low surgical invasiveness, consultants and ASA members agree that the interview and physical examination may be done on or before the day of surgery.

A majority of consultants and the ASA membership, respectively, agree that, *at a minimum*, a preanesthesia physical examination should include (1) an airway exam

Table 2. Timing of the Preanesthetic Interview and Physical Examination—Survey Opinions

| High Severity of Disease | Surgical Invasiveness | | | | | |
|---------------------------------|-------------------------|--------------------------|-------------------------|--------------------------|-------------------------|--------------------------|
| | High | | Medium | | Low | |
| | Consultants (N = 72) | ASA Members (N = 232) | Consultants (N = 72) | ASA Members (N = 232) | Consultants (N = 72) | ASA Members (N = 232) |
| Prior to the day of surgery | 96% | 89% | 94% | 69% | 71% | 53% |
| On or before the day of surgery | 4% | 9% | 4% | 28% | 24% | 32% |
| Only on the day of surgery | 0% | 2% | 1% | 3% | 5% | 15% |
| Low Severity of Disease | Surgical Invasiveness | | | | | |
| | High | | Medium | | Low | |
| | Consultants (N = 72) | ASA Members (N = 229) | Consultants (N = 72) | ASA Members (N = 229) | Consultants (N = 72) | ASA Members (N = 229) |
| Prior to the day of surgery | 72% | 53% | 29% | 21% | 13% | 25% |
| On or before the day of surgery | 11% | 20% | 49% | 46% | 39% | 34% |
| Only on the day of surgery | 15% | 11% | 21% | 34% | 47% | 56% |

ASA = American Society of Anesthesiologists.

(100%, 100%), (2) a pulmonary examination to include auscultation of the lungs (88%, 85%), and (3) a cardiovascular examination (81%, 82%).

Advisory

The Task Force consensus is that an assessment of readily accessible, pertinent medical records with consultations, when appropriate, should be performed as part of the preanesthesia evaluation prior to the day of surgery for procedures with high surgical invasiveness. For procedures with low surgical invasiveness, the review and assessment of medical records may be done on or before the day of surgery by anesthesia staff. The information obtained may include, but should not be limited to (1) a description of current diagnoses, (2) treatments, including medications and alternative therapies used, and (3) determination of the patient's medical condition(s). Public commentary at open forums and from the Internet corroborates the Task Force consensus.

The Task Force consensus is that an initial record review, patient interview, and physical examination should be performed prior to the day of surgery for patients with high severity of disease. For patients with low severity of disease and undergoing procedures with high surgical invasiveness, the interview and physical exam should also be performed prior to the day of surgery. For patients with low severity of disease undergoing procedures with medium or low surgical invasiveness, the initial interview and physical exam may be performed on or before the day of surgery.

At a minimum, a focused preanesthesia physical examination should include an assessment of the airway, lungs, and heart, with documentation of vital signs. Public commentary at open forums and from the Internet corroborate the Task Force opinions.

The Task Force cautions that timing of preanesthesia assessments may not be practical with the current limitation of resources provided by a specific healthcare system or practice environment. The Task Force believes it is the obligation of the healthcare system to, at a minimum, provide pertinent information to the anesthesiologist for the appropriate assessment of the severity of the medical condition of the patient and invasiveness of the proposed surgical procedure well in advance of the anticipated day of the procedure for all elective patients.

Selection and Timing of Preoperative Tests

Literature regarding controlled trials and test findings regarding the incidence or frequency of commonly used preoperative tests are described below. For purposes of this Advisory, a *routine* test is defined as a test ordered in the absence of a specific clinical indication or purpose. Global designations such as "preop status" or "sur-

gical screening" are not considered as specific clinical indications or purposes. An *indicated* test is defined as a test that is ordered for a specific clinical indication or purpose. For example, assessment of warfarin therapy effects would be considered an indication for specific coagulation studies.

Electrocardiogram. Routine electrocardiographic findings were reported as abnormal in 7.0-42.7% of cases (N = 12 studies)⁹²⁻¹⁰³ and led to changes in clinical management in 9.1% of the cases found to be abnormal (N = 1 study).¹⁰⁰ Preoperative electrocardiograms that were ordered as indicated tests resulted in reports of abnormal findings in 4.8-78.8% of cases (N = 17 studies)^{49,51,82,100,104-116} and led to changes in clinical management in 2.0-20.0% of the cases found to be abnormal (N = 6 studies).^{49,82,100,104,111,112} One observational study with investigator and practitioner blinding found that preoperative electrocardiographic ischemic episodes were associated with intra- and postoperative myocardial infarction for older patients with severe coronary artery disease scheduled for elective coronary artery bypass grafting (CABG).¹¹⁰ One observational study reported a 10% or greater incidence of coronary events during the subsequent 10 yr for men over 60 without specific clinical indicators and for women over 65 without specific clinical indicators. The incidence increased to 25% in the decade after such patients' seventy-fifth birthday.¹⁰⁷

Other Cardiac Evaluation. No studies were found that examined outcomes from routine preoperative cardiac evaluations of angiography, echocardiography, or stress tests. For patients with indicated cardiac evaluations, abnormal findings were found with angiography: 22.5-47.0% of cases (N = 4 studies)¹¹⁷⁻¹²⁰; echocardiography: 7.5%-50.0% of cases (N = 5 studies)¹²¹⁻¹²⁵; stress or exercise tests: 15.0-71.0% of cases (N = 3 studies).^{105,126,127} Changes in clinical management were not uniformly reported.

Chest X-ray. Routine chest x-ray findings were reported as abnormal in 2.5-60.1% of cases (N = 20 studies)^{96,98,100,102,128-142} and led to changes in clinical management in 0-51% of the cases found to be abnormal (N = 9 studies).^{100,102,128,129,136,139-142} For patients with indicated preoperative chest x-rays, abnormal findings were reported in 7.7-65.4% of cases (N = 18 studies)^{30,82,92,100,106,112,128,137,143-152} and led to changes in clinical management in 0.5-74.3% of the cases found to be abnormal (N = 9 studies).^{82,100,112,128,143,145-147,152} Two nonrandomized studies compared asymptomatic patients receiving chest x-rays *versus* asymptomatic patients not receiving chest x-rays and found no differences in delays or cancellations of surgery.^{141,142} However, the studies found that an abnormal preoperative chest x-ray finding altered care in 8.6% and 9.9% of the cases found to be abnormal.

Pulmonary Evaluation (i.e., Pulmonary Function Tests, Spirometry). Studies examining routine pulmonary function tests (PFT's) did not contain data on abnormal findings (N = 2).^{46,153} Studies examining routine preoperative spirometry reported abnormal findings in 15.0-51.7% of cases (N = 3 studies).¹⁵⁴⁻¹⁵⁶ Findings for indicated preoperative PFT's were reported as abnormal in 17.0-27.1% of cases (N = 3 studies),¹⁵⁷⁻¹⁵⁹ and indicated preoperative spirometry (a limited form of PFT's) were reported as abnormal in 33.1-45.0% of cases (N = 3 studies).^{30,157,160} Changes in clinical management were not reported. No studies were found that reported results of routine preanesthesia office spirometry (i.e., portable or hand held spirometers).

Hemoglobin and Hematocrit Measurement. Routine hemoglobin measurements were reported as abnormal in 0.5-43.8% of cases (N = 7 studies)^{102,133,161-165} and led to changes in clinical management in 0%-28.6% of the cases found to be abnormal (N = 3 studies).^{102,161,164} Indicated hemoglobin measurements were reported as abnormal in 38.6-62.0% of cases (N = 2 studies).^{166,167} Changes in clinical management were not reported.

Routine hematocrit measurements were reported as abnormal in 0.2-38.9% of cases (N = 5 studies)^{136,162,168-170} and led to changes in clinical management in 0-100% of the cases found to be abnormal (N = 3 studies).^{136,168,170} Indicated hematocrit measurements were reported as abnormal in 0.4-5.0% of cases (N = 2 studies).^{51,148} Changes in clinical management were not reported.

In studies reporting routine complete blood counts (i.e., individual test results not reported), abnormal findings were reported in 2.9-17.6% of cases (N = 4 studies)^{92,98,171-172} and led to changes in clinical management in 2.4% of the cases found to be abnormal (N = 1 study).¹⁷² For indicated complete blood counts, abnormal findings were reported in 6.3-60.8% of cases (N = 4 studies)^{92,107,108,112} and led to changes in clinical management in 0.0%-14.9% of the cases found to be abnormal (N = 2 studies).^{108,112}

Coagulation Studies. Routine coagulation studies reported abnormalities in bleeding time, prothrombin time, partial prothrombin time, or platelet count in 0.8-22.0% of cases (N = 15 studies)^{13,136,162,173-184} and led to changes in clinical management in 1.1-4.0% of the cases found to be abnormal (N = 2 studies).^{13,136} Findings for indicated coagulation studies were reported as abnormal in 3.4-29.1% of cases (N = 4 studies).^{183,185-187} Changes in clinical management were not reported. The incidence of routine coagulation study abnormalities in patients scheduled for regional anesthesia or postoperative analgesia in surgical patients has not been reported. The incidence of routine coagulation study abnormalities in obstetric patients has not been reported.

Serum Chemistries. In routine preoperative potassium tests, abnormal levels of potassium were found in 1.5-12.8% of cases (N = 3 studies).^{133,162,188} For indicated potassium tests, abnormal levels were found in 1.0-29.5% of cases (N = 4 studies).^{51,148,189,190} One randomized clinical trial compared preoperative serum potassium levels at induction with serum potassium levels 3 days before surgery, and found lower potassium levels (hypokalemia) at induction.¹⁸⁸ No blinded studies were found that assessed the benefits or harms of practitioner awareness of potassium abnormalities.

In routine preoperative glucose tests in nondiabetic patients or patients without altered glucose metabolism, abnormal levels of glucose were found in 5.4-13.8% of cases (N = 3 studies).^{133,162,171} Changes in clinical management were not reported.

Urine Testing. In routine preoperative urinalysis (not including pregnancy testing), abnormal results were reported in 0.7-38.0% of cases (N = 9 studies)^{92,96,102,136,162,170,172,191,192} and led to changes in clinical management in 2.3-100% of the cases found to be abnormal (N = 6 studies).^{102,136,170,172,191,192} For indicated urinalysis, abnormal results were found in 4.6-42.0% of cases (N = 4 studies)^{92,108,112,148} and led to changes in clinical management in 0.0-23.1% of the cases found to be abnormal (N = 2 studies).^{108,112}

Pregnancy Testing. Routine pregnancy tests (routine refers to premenopausal menstruating females, not excluding anyone on the basis of history) resulted in positive findings in 0.3-2.2% of cases (N = 5 studies)¹⁹³⁻¹⁹⁷ and led to changes in clinical management, delays or cancellation of surgery in 100% of the cases found to be pregnant.

Consultants and ASA members were asked to consider whether specific preoperative tests should be conducted (1) on a routine basis (i.e., given to patients regardless of known or suspected diseases or disorders), (2) for selected patients or for selected types of surgery, or (3) the test is not necessary. For the tests considered, consultant and ASA membership responses are reported in table 3. Consultants and ASA members were also asked to identify specific patient characteristics that would favor a decision to order, require, or perform a preoperative test. For these specific patient characteristics, consultant and ASA membership responses are reported in table 4.

Consultants and ASA members were asked whether selected preoperative tests are acceptable if obtained from the patient's medical chart, assuming the patient's medical history has not changed substantially since the test was obtained. Majority opinions of consultants and ASA members are reported as percentage agreement, respectively, as follows:

1. Electrocardiogram (99%, 98%)
2. Other cardiac evaluation (94%, 98%)
3. Chest x-ray (97%, 92%)

Table 3. Routine or Selective Preoperative Testing—Survey Opinions

| Preoperative Test | All Patients (Routine) % Agreement* | Selected Patients % Agreement | Test Not Necessary % Agreement |
|--|--|----------------------------------|-----------------------------------|
| Electrocardiogram | 0 | 100% | 0 |
| Consultants (N = 72) | 1% | 98% | 1% |
| ASA members (N = 233) | | | |
| Cardiac tests other than electrocardiogram | 0 | 97% | 0 |
| Consultants (N = 72) | 1% | 99% | 0 |
| ASA members (N = 233) | | | |
| Chest x-rays | 3% | 90% | 7% |
| Consultants (N = 72) | 1% | 92% | 6% |
| ASA members (N = 233) | | | |
| Pulmonary function tests | 0 | 98% | 2% |
| Consultants (N = 42) | 0 | 96% | 3% |
| ASA members (N = 234) | | | |
| Office spirometry | 0 | 88% | 10% |
| Consultants (N = 42) | 1% | 63% | 20% |
| ASA members (N = 234) | | | |
| Hemoglobin/hematocrit | 3% | 96% | 1% |
| Consultants (N = 72) | 4% | 95% | 1% |
| ASA members (N = 234) | | | |
| Coagulation studies | 3% | 94% | 1% |
| Consultants (N = 72) | 1% | 98% | 1% |
| ASA members (N = 234) | | | |
| Serum chemistries | 1% | 99% | 0 |
| Consultants (N = 72) | 1% | 99% | 0 |
| ASA members (N = 234) | | | |
| Urinalysis | 1% | 53% | 46% |
| Consultants (N = 72) | 2% | 47% | 49% |
| ASA members (N = 233) | | | |
| Pregnancy test | 7% | 88% | 5% |
| Consultants (N = 72) | 17% | 78% | 3% |
| ASA members (N = 232) | | | |

* Row percentages do not include "don't know" responses, therefore row totals may not equal 100%.

ASA = American Society of Anesthesiologists.

4. Hemoglobin/hematocrit (99%, 96%)
5. Coagulation studies (86%, 98%)
6. Serum chemistries (96%, 98%)

Respondents who agreed that test findings might be obtained from a patient's medical chart were asked how recent the findings should be in order to be acceptable. Opinions on how recent test findings should be are reported in table 5.

Advisory

Routine Preoperative Testing

The current literature is not sufficiently rigorous to permit an unambiguous assessment of the clinical benefits or harms of routine preoperative tests. The studies examined by the Task Force reported a wide range of abnormal results associated with preoperative testing. When abnormal or positive results were found, the percentage of patients with subsequent changes in their clinical management varied widely.

The Task Force agrees with the consultants and ASA members that preoperative tests should not be ordered routinely. The Task Force agrees that preoperative tests may be ordered, required, or performed on a *selective basis* for purposes of guiding or optimizing perioperative management. The indications for such testing

should be documented and based on information obtained from medical records, patient interview, physical examination, and type and invasiveness of the planned procedure. Public commentary from open forums corroborates the Task Force consensus.

Preoperative Testing in the Presence of Specific Clinical Characteristics

The current literature is not sufficiently rigorous to permit an unambiguous assessment of the clinical benefits or harms associated with selected preoperative test findings. The studies examined by the Task Force reported a wide range of abnormal preoperative test results. In addition, when abnormal or positive results were found, the percentage of patients with subsequent changes in their clinical management varied widely. Few randomized controlled trials were found that examined the outcomes for patients who had *routine* preoperative tests compared with outcomes for patients with *indicated* preoperative tests.¹⁹⁸

The Task Force believes that there is insufficient evidence to identify explicit decision parameters or rules for ordering preoperative tests on the basis of specific clinical characteristics. However, the Task Force believes that consideration of selected clinical characteristics

Table 4. Patient Characteristics for Selected Preoperative Testing

| Preoperative Test | Patient Characteristics | Consultants (N = 72) | ASA Members (N = 234) |
|--|---|-------------------------|--------------------------|
| Electrocardiogram | Advanced age | 93% | 94% |
| | Cardiocardiac disease | 97% | 98% |
| | Respiratory disease | 74% | 74% |
| Other cardiac evaluation (e.g. stress test) | Cardiovascular compromise | 88% | 95% |
| | Recent upper respiratory infection | 45% | 59% |
| Chest radiograph | Smoking | 42% | 60% |
| | COPD | 71% | 76% |
| | Cardiac disease | 62% | 75% |
| Pulmonary function tests | Reactive airway disease | 68% | 71% |
| | COPD | 80% | 89% |
| | Scoliosis | 53% | 60% |
| Office spirometry (i.e. portable spirometer) | Reactive airway disease | 83% | 86% |
| | COPD | 77% | 90% |
| | Scoliosis | 51% | 52% |
| Hemoglobin/hematocrit | Advanced age | 57% | 68% |
| | Very young age | 52% | 56% |
| | Anemia | 96% | 99% |
| Coagulation studies | Bleeding disorders | 93% | 94% |
| | Other hematological disorders | 74% | 84% |
| | Bleeding disorders | 99% | 98% |
| Serum chemistries (sodium, potassium, carbon dioxide, chloride, glucose) | Renal dysfunction | 40% | 52% |
| | Liver dysfunction | 97% | 91% |
| | Anticoagulants | 97% | 96% |
| Pregnancy test | Endocrine disorders | 93% | 95% |
| | Renal dysfunction | 96% | 98% |
| | Medications | 87% | 89% |
| | Uncertain pregnancy history | 84% | 91% |
| | History suggestive of current pregnancy | 94% | 96% |

ASA = American Society of Anesthesiologists; COPD = chronic obstructive pulmonary disease.

tics may assist the anesthesiologist when deciding to order, require, or perform preoperative tests. The following clinical characteristics may be of merit, although anesthesiologists should not limit their consideration only to those suggested below.

Electrocardiogram. The Task Force agrees that important clinical characteristics may include cardiocirculatory disease, respiratory disease, and type or invasive-

ness of surgery. The Task Force recognizes that electrocardiogram abnormalities may be higher in older patients and in patients with multiple cardiac risk factors.

No consensus was obtained from the consultants and ASA membership regarding a minimum age for obtaining a preanesthesia electrocardiogram. The Task Force did not reach consensus on a specific minimum age in those

Table 5. Timing of Test Findings—Survey Opinions

| Preoperative Test | 24 h | 48 h | 1 wk | 2 wk | 1 mo | 3 mo | 6 mo | 1 yr | >1 yr |
|-----------------------|-----------------------|------|------|------|------|------|------|------|-------|
| Electrocardiogram | | | | | | | | | |
| | Consultants (N = 72) | 0 | 0 | 4% | — | 31% | — | 46% | 19% |
| Other cardiac tests | ASA members (N = 218) | 1% | 0 | 6% | — | 34% | — | 45% | 12% |
| | Consultants (N = 72) | 0 | 0 | 5% | — | 33% | — | 27% | 26% |
| Chest x-ray | ASA members (N = 217) | 0 | 0 | 7% | — | 33% | — | 40% | 18% |
| | Consultants (N = 72) | 0 | 5% | 5% | — | 25% | 23% | 19% | 23% |
| Hemoglobin/hematocrit | ASA members (N = 206) | 0 | 2% | 8% | — | 27% | 9% | 31% | 23% |
| | Consultants (N = 72) | — | — | 14% | 8% | 42% | 23% | 8% | 5% |
| Coagulation studies | ASA members (N = 213) | — | — | 13% | 11% | 46% | 17% | 11% | 1% |
| | Consultants (N = 42) | 28% | 11% | 30% | 6% | 19% | 6% | — | — |
| Serum chemistries | ASA members (N = 194) | 33% | 16% | 26% | 6% | 16% | 4% | — | — |
| | Consultants (N = 72) | 15% | 7% | 27% | 17% | 27% | 7% | — | — |
| | ASA members (N = 203) | 11% | 12% | 26% | 9% | 34% | 7% | — | — |

ASA = American Society of Anesthesiologists.

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patients without specific risk factors. The Task Force recognizes that age alone may not be an indication for an electrocardiogram. The Task Force agrees that an electrocardiogram may be indicated for patients with known cardiovascular risk factors or for patients with risk factors identified in the course of a preanesthesia evaluation.

Preanesthesia Cardiac Evaluation (other than Electrocardiogram). Preanesthesia cardiac evaluation may include consultation with specialists and ordering, requiring, or performing tests that range from noninvasive passive or provocative screening tests (e.g., stress testing) to noninvasive and invasive assessment of cardiac structure, function, and vascularity (e.g., echocardiogram, radionuclide imaging, cardiac catheterization). Anesthesiologists should balance the risks and costs of these evaluations against their benefits. Clinical characteristics to consider include cardiovascular risk factors and type of surgery.

Preanesthesia Chest Radiographs (X-ray). Clinical characteristics to consider include smoking, recent upper respiratory infection, chronic obstructive pulmonary disease (COPD), and cardiac disease. The Task Force recognizes that chest radiographic abnormalities may be higher in such patients, but does not believe that extremes of age, smoking, stable COPD, stable cardiac disease, or resolved recent upper respiratory infection should be considered unequivocal indications for chest radiography.

Preanesthesia Pulmonary Evaluation (other than Chest X-ray). Preanesthesia pulmonary evaluation other than chest x-ray may include consultation with specialists and tests that range from noninvasive passive or provocative screening tests (e.g., pulmonary function tests, spirometry, pulse oximetry) to invasive assessment of pulmonary function (e.g., arterial blood gas). Anesthesiologists should balance the risks and costs of these evaluations against their benefits. Clinical characteristics that the Task Force believes should be considered include type and invasiveness of the surgical procedure, interval from prior evaluation, treated or symptomatic asthma, symptomatic COPD, and scoliosis with restrictive function.

Preanesthesia Hemoglobin or Hematocrit. The Task Force believes that routine hemoglobin or hematocrit is not indicated. Clinical characteristics to consider as indications for such tests include type and invasiveness of procedure, patients with liver disease, extremes of age, history of anemia, bleeding, and other hematologic disorders.

Preanesthesia Coagulation Studies (e.g., INR, PT, PTT, platelets). Clinical characteristics to consider for ordering selected coagulation studies include bleeding disorders, renal dysfunction, liver dysfunction, and type and invasiveness of procedure. The Task Force recognizes that anticoagulant medications and alternative ther-

apies may present an additional perioperative risk. The Task Force believes that there were not enough data to comment on the advisability of coagulation tests before regional anesthesia. The Task Force strongly recommends appropriately controlled studies of such specific indications.

Preanesthesia Serum Chemistries (i.e., Potassium, Glucose, Sodium, Renal and Liver Function Studies). The Task Force recognizes that laboratory values may differ from normal values at extremes of age. Clinical characteristics to consider before ordering such tests include likely perioperative therapies, endocrine disorders, risk of renal and liver dysfunction, and use of certain medications or alternative therapies.

Preanesthesia Urinalysis. The consensus of the Task Force is that urinalysis is not indicated except for specific procedures (e.g., prosthesis implantation, urologic procedures) or when urinary tract symptoms are present.

Preanesthesia Pregnancy Testing. The Task Force recognizes that a history and physical examination may be insufficient for identification of early pregnancy. Pregnancy testing may be considered for all female patients of childbearing age. Clinical characteristics to consider include an uncertain pregnancy history or a history suggestive of current pregnancy.

Timing of Preoperative Testing

The current literature is not sufficiently rigorous to permit an unambiguous assessment of the clinical benefits or harms of the timing for preoperative tests. The Task Force believes that there is insufficient evidence to identify explicit decision parameters or rules for ordering preoperative tests on the basis of specific patient factors.

The Task Force believes that test results obtained from the medical record within 6 months of surgery are generally acceptable if the patient's medical history has not changed substantially. More recent test results may be desirable when the medical history has changed, or when test results may play a role in the selection of a specific anesthetic technique (e.g., regional anesthesia in the setting of anticoagulation therapy.) Public commentary from open forums and from the Internet corroborates the Task Force consensus.

Summary and Conclusions

A preanesthesia evaluation involves the assessment of information from multiple sources, including medical records, patient interviews, physical examinations, and findings from preoperative tests.

The current scientific literature does not contain sufficiently rigorous information about the components of a preanesthesia evaluation to permit recommendations

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that are unambiguously based. Therefore, the Task Force has relied primarily upon noncontrolled literature, opinion surveys of consultants, and opinion surveys of a random sample of members of the ASA. The focus of opinion surveys has been threefold (1) the content of the preanesthesia evaluation, (2) the timing of the preoperative evaluation, and (3) the indications for specific preoperative tests.

The following remarks represent a synthesis of the opinion surveys, literature and Task Force consensus:

1. *Content* of the preanesthesia evaluation includes but is not limited to (1) readily accessible medical records, (2) patient interview, (3) a directed preanesthesia examination, (4) preoperative tests when indicated, and (5) other consultations when appropriate. At a *minimum*, a directed preanesthesia physical examination should include an assessment of the airway, lungs, and heart.
2. *Timing* of the preanesthesia evaluation can be guided by considering combinations of surgical invasiveness and severity of disease, as shown in table 2. The Task Force cautions that limitations in resources available to a specific healthcare system or practice environment may impact the timing of the preanesthesia evaluation. The healthcare system is obligated to provide pertinent information to the anesthesiologist for the appropriate assessment of the invasiveness of the proposed surgical procedure and the severity of the patient's medical condition well in advance of the anticipated day of procedure for all elective patients.
3. *Routine preoperative tests* (i.e., tests intended to discover a disease or disorder in an asymptomatic patient) do not make an important contribution to the process of perioperative assessment and management of the patient by the anesthesiologist.
4. *Selective preoperative tests* (i.e., tests ordered after consideration of specific information obtained from sources such as medical records, patient interview, physical examination, and the type or invasiveness of the planned procedure and anesthesia) may assist the anesthesiologist in making decisions about the process of perioperative assessment and management.
5. *Decision-making parameters* for specific preoperative tests or for the timing of preoperative tests cannot be unequivocally determined from the available scientific literature. Further research is needed, preferably in the form of appropriately randomized clinical trials. Specific tests and their timing should be individualized and based upon information obtained from sources such as the patient's medical record, patient interview, physical examination, and the type and invasiveness of the planned procedure.

The references listed here do not represent a complete bibliography of the literature reviewed. A complete bibliography is available by writing to the American Society of Anesthesiologists or by accessing the ANESTHESIOLOGY Web site: <http://www.anesthesiology.org>.

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